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*ADMITTED IN DC ONLY

March 9, 2017

Re: UMB Bank, N.A., as Trustee v. Sanofi, 15 Civ. 8725 (S.D.N.Y.) (GBD)

Dear Judge Daniels:

We represent Plaintiff UMB Bank, N.A., as Trustee, and write to request a pretrial conference at the Court's earliest convenience in order to discuss the following four items:

1. **The Filing of an Additional Lawsuit**.

The Trustee acts in favor of each person who from time to time holds one or more of the Contingent Value Rights (each a "CVR") issued pursuant to the Contingent Value Rights Agreement (the "CVR Agreement"; copy attached). Each CVR represents the right for its holder to receive certain payments upon the achievement of: (i) specified Product Approval and Product Sales Milestones related to the regulatory approval and revenue ramp for a drug known as Lemtrada®[1]; and (ii) a separate Production Milestone related to the production of two unrelated and previously approved drugs known as Cerezyme®[2] and Fabrazyme®[3]. Sanofi agreed to pay up to $14.00 per CVR (or a total of roughly $4 billion) to CVR holders upon achievement of these milestones. In 2015, the Trustee commenced the above-captioned action relating to Sanofi's failure on a timely basis to develop and commercialize Lemtrada®.[4] The Trustee is

[1] Lemtrada® is the brand name for alemtuzumab when indicated for the treatment of relapsing remitting multiple sclerosis.

[2] Cerezyme® is the brand name for an enzyme known as imiglucerase and is used for the treatment of Gaucher Disease

[3] Fabrazyme® is the brand name for agalsidase beta and is used for the treatment of Fabry Disease.

[4] *See American Stock Transfer & Trust Company, LLC, as Trustee* v. *Sanofi*, 1:15-cv-08725 (S.D.N.Y.) (GBD) (the "Lemtrada® Action"). On July 19, 2016, UMB was substituted as Trustee for American Stock Transfer & Trust Company, LLC and the lawsuit concerning the Lemtrada® milestones in now captioned *UMB Bank, N.A., as Trustee* v. *Sanofi*, 1:15-cv-08725 (S.D.N.Y.) (GBD).

now prepared to file a breach of contract lawsuit concerning Sanofi's separate and distinct failures on a timely basis to achieve stated production levels of Cerezyme® and Fabrazyme® (the "Cerezyme® and Fabrazyme® Action").[5]

The Trustee requests an opportunity to discuss with the Court whether the Court would wish the two actions to be designated as "related" for purposes of case assignment. The two actions (which involve different obligations with respect to different drugs and different milestones) are not necessarily related for purposes of case assignment. However, if Your Honor would wish the Trustee to designate the to-be-filed Cerezyme® and Fabrazyme® Action as "related" to the pending Lemtrada® Action, the Trustee will do so.

2. The Trustee's Right to Examine Books and Records and Conduct an Audit.

Separate and distinct from the right to sue Sanofi for breach, Section 4.2(f) of the CVR Agreement entitles the Trustee to examine the books, records and premises of Sanofi to assure Sanofi's compliance with its obligations under the CVR Agreement, and Section 7.6(a) requires Sanofi to comply with audit requests of its Product Sales Statements. Section 4.2(f) provides:

> the Trustee in its discretion may make such further inquiry or investigation into such facts or matters as it may see fit, and if the Trustee shall determine to make such further inquiry or investigation, it shall be entitled to examine the books, records and premises of [Sanofi], personally or by agent or attorney, as necessary for such inquiry or investigation at the sole cost of [Sanofi] . . . .

Section 7.6(a) provides:

> Upon the request of the Acting Holders (but no more than once during any calendar year), and upon reasonable notice, [Sanofi] shall provide an independent certified public accounting firm of nationally recognized standing jointly agreed upon by the Acting Holders and [Sanofi] . . . with access during normal business hours to such of the records of [Sanofi] as may be reasonably necessary to verify the accuracy of the statements set forth in the Product Sales Statements and the figures underlying the calculations set forth therein for any period within the preceding three (3) years . . . .

By letters dated December 9, 14 and 19, 2016, and in a face-to-face meet and confer on February 15, 2017 and follow-ups relating thereto, the Trustee informed Sanofi of its desire to exercise its examination and audit rights under Sections 4.2(f) and 7.6(a). Access is needed to verify what Sanofi is saying about product sales, and to address Sanofi's arithmetic gymnastics in its use of foreign exchange rates and "adjustments" in connection with its translation of sales in foreign currencies to U.S. dollars for application to the thresholds in the CVR Agreement. Sanofi has refused to permit the Trustee access to its books, records and premises, or to submit to an audit.

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[5] The Trustee continues to investigate additional potential claims against Sanofi with respect to the negotiation, execution and compliance with CVR Agreement as it relates to the Production Milestone.

The Trustee requests an opportunity to discuss with the Court the setting of a schedule for a motion compelling Sanofi to comply with its obligations under Sections 4.2(f) and 7.6(a), and permit the Trustee to examine the books, records and premises of Sanofi relevant to Sanofi's obligations under the CVR Agreement and submit to an independent audit of its Product Sales Statements. Prior to any such audit, the parties will agree to the appropriate scope, including, without limitation, guidance on the definition of the term Product Launch, the applicable interest rate, and other terms, with assistance from the Court as required. This issue is time-sensitive and also relates to Item 3 discussed immediately below.

3. The Failure Purchase Option.

Article 10 of the CVR Agreement allows Sanofi to redeem the CVRs at a price defined in the CVR Agreement if, after the third anniversary after the Product Launch of Lemtrada®, both (i) the volume weighted average trading price of the CVR over a 45 trading-day period is less than $0.50 and (ii) Lemtrada® sales in a trailing four calendar quarter period prior to that date are less than $1 billion (a "Failure Purchase Eligibility Date"). This is referred to as a Failure Purchase, and its proper exercise results in the cancelation of all CVRs.

It is Sanofi's position that the Product Launch of Lemtrada® is deemed to have occurred on April 1, 2014, and that the third anniversary thereof (April 1, 2017) is the Failure Purchase Eligibility Date under the CVR Agreement. Whether the Product Launch date is or should be deemed to be April 1, 2014 is central to any assessment of whether the Failure Purchase can even be triggered as early as next month, and that is a subject of dispute. While Sanofi asserts that Product Launch occurred on April 1, 2014 due to "sales" of Lemtrada® in Germany in the fourth quarter of 2013, this does not determine the issue. First, there is the question of whether those sales qualify under the CVR Agreement. Second, there is the question as to whether Sanofi should be credited with those sales if they were made with the intention of accelerating the Product Launch date, while holding off sales in the rest of the world. Only an audit and discovery can answer these questions.

The recent CVR trading price is below $0.50, artificially depressed because of Sanofi's wrongful conduct. We have raised the issue of whether Sanofi plans to exercise the Failure Purchase with Sanofi's counsel but have received no answer on the matter. The examination of books and records and audit discussed in Item 2 above is necessary because there is a question of whether the Product Launch of Lemtrada® in fact occurred on April 1, 2014, whether the Lemtrada® sales condition of the Failure Purchase is satisfied, or if numerically satisfied is so only because of Sanofi's breach of its obligations under the CVR Agreement.

But whether or not the conditions for the exercise of the Failure Purchase are technically satisfied, it is well-settled under New York law that a party should not be permitted to benefit from its own contractual breach. A party in breach cannot be permitted to escape litigation over its wrongful conduct by benefitting from the exercise of an option that its wrongful conduct created.

4. Discovery / Scheduling and the Appointment of a Special Master.

Lastly, the Trustee wishes to apprise the Court of the status of discovery, and to discuss scheduling for the remaining pre-trial proceedings and the appointment of a Special Master to oversee discovery and, perhaps, facilitate settlement discussions. By the time my law firm was substituted in as counsel for the Trustee, Sanofi had purported to produce on the order of 11 million pages of documents. As it turned out, approximately 90% of that tonnage was the purported eCTD e-filing that Sanofi made with the FDA relating to Lemtrada®. Your Honor will recall that the FDA rejected Sanofi's eCTD e-filing as not properly assembled and that rejection caused a delay that, by itself, virtually assured that Sanofi would not meet several of the milestones in the CVR Agreement. That eCTD filing is core, indeed critical, evidence in this case. But, after we reviewed the 11 million documents it was apparent to us that the file as produced by Sanofi to the Trustee was not what had been filed with the FDA. It was not a live, navigable file as required by the FDA rules, and in large part was unintelligible, as if instead of providing a book one provided a mountain of letters. We discussed this with counsel for Sanofi in both correspondence and a face-to-face meet and confer. Counsel for Sanofi did not dispute the problem with their production and set about correcting it. Monday, we received a hard drive from counsel for Sanofi that purportedly replaces 90% of their prior production in native format. This huge production error, which is not the Trustee's doing, has set the case back in terms of scheduling. Even as of this date, the Trustee has received little to nothing from Sanofi of the negotiating and drafting history of the CVR Agreement, and only in the last two weeks has Sanofi agreed that the files of its corporate counsel (which also serves as its litigation counsel in this action) will be searched and an appropriate production made.

The Trustee would like to discuss with the Court the appointment of a Special Master, experienced in FDA product approval, production, development and commercialization, to oversee discovery in this matter and facilitate settlement discussions between the parties.

We are at the Court's convenience to discuss the foregoing.

Respectfully submitted,

Charles A. Gilman

Hon. George B. Daniels
United States District Judge
Southern District of New York
500 Pearl Street
New York, New York 10007-1312
Via ECF and Electronic Mail
cc: Counsel of Record